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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/803,512

03/18/2004

Guy Rome

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34284

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05/24/2010

Rutan & Tucker, LLP.

611 ANTON BLVD

SUITE 1400

COSTA MESA, CA 92626

EXAMINER

VU, QUYNH-NHU HOANG

ART UNIT

PAPER NUMBER

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/803,512	Applicant(s) ROME, GUY	
	Examiner QUYNH-NHU H. VU	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 March 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 30-47 is/are pending in the application.
- 4a) Of the above claim(s) 34-39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 30-33 and 40-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>3/22/10 & 3/22/10</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Response to Amendment

Amendment and Request for Continued Examination (RCE) filed on 03/22/10 have been entered.

Claims 30-33, 40-47 are present for examination.

Claims 34-39 are withdrawn.

Claims 1-29 are cancelled.

Drawings

The drawings 7A-C (elected Species) are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "built-in valve having a closed proximal end with a slit and an open distal end" must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

As noted that the built-in valve 206 with a slit shows in non-elected Figs. 4A-E but not in the elected Figs. 7A-C.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

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Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 30 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Nowhere in the Specification or elected Species of Figs. 7A-C show that limitation "a built-in valve having a closed proximal end with a slit and an open distal end". As noted, the limitation above only shows in Figs. 4A-E that: "a built-in valve 206 having a closed proximal end with a slit and an open distal end." However, the Figs. 4A-E is non-Elected Species, see Restriction/Election mailed out 03/07/09 and Response to Restriction/Election filed in 04/27/09.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 30-32, 40-41, 44-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lampropoulos et al. (US 6,402,723) in view of Newgard et al. (US 4,874,377).

Regarding claims 30 and 44-45, Lampropoulos discloses, in Fig. 6, a catheter assembly, comprising: a catheter 112 including at least one lumen; and a connector (element 38 and 41 formed the connector) including a distal end 31 attached to a proximal end 116 of the catheter and a passageway in fluid communication with the at least one lumen, a proximal portion 29 of the passageway including an engagement feature 29 configured to connect an end of an instrument 114 to the connector, a distal

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portion 18 of the passageway including a valve (including elements 80 and 14) longitudinally fixed with respect to the connector, the valve proximal end distal of the engagement feature.

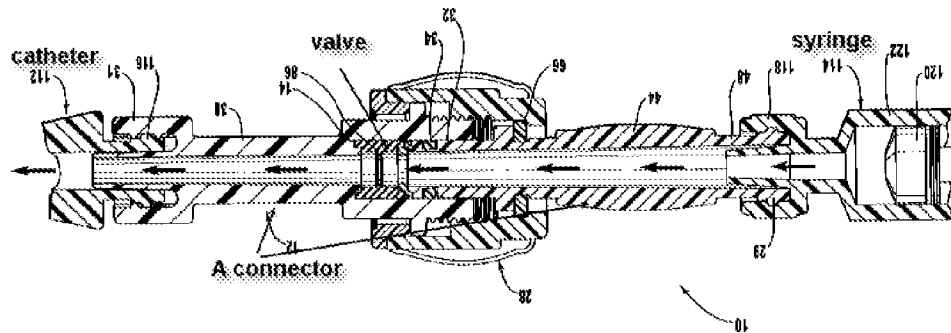


Fig. 6 flipped side

Lampropoulos does not disclose that the valve built-in having a closed proximal end with a slit and an open distal end; wherein the valve proximal end is fixed with res

Newgard discloses a catheter assembly comprising: a catheter/cannula 30; a connector 16; a valve 48 longitudinal connected with the connector 16; wherein the valve having a closed proximal end with a slit 64 and open distal end, (see Fig. 3), the valve 48 proximal end distal of the engagement feature 70, see Fig. 4 below.

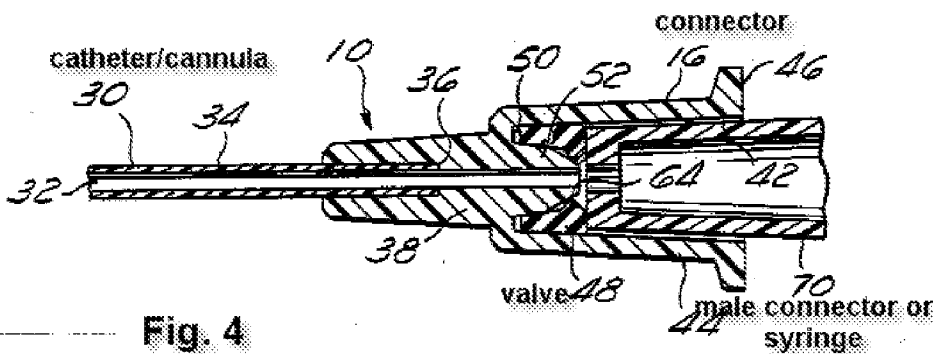


Fig. 4

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of Lampropoulos with a slit valve, as taught by Newgard, in order to prevent the fluid back flow therethrough.

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With respect to the limitation "built-in", it would have been obvious to one having ordinary skill in the art at the time the invention was made to the built-in valve, since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art.

Regarding claim 31, Lampropoulos shows that the valve includes a wall defining a lumen from the proximal end to the distal end, the wall configured to guide a proximal end of a guidewire from the valve distal end through the slit in the valve proximal end, Fig. 5. Alternatively, Newgard shows the needle 60 inserted through the valve 48. One skill in the art would recognize that the wall of the valve is capable or adapted to guide a proximal end of the guidewire from the valve distal end through the valve proximal end.

Regarding claim 32, Lampropoulos in view of Newgard discloses the claimed invention except for that the connector comprise a material having a hardness in the range of about 90 Shore A to about 90 Shore D, and wherein the valve comprises a material having a hardness in the range of about 40 Shore A to about 60 Shore A.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the material of connector and valve as listed above, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Regarding claim 40, Lampropoulos further shows that the connector (portion 44) includes an tapered outer surface 44 at a proximal end thereof.

Regarding claim 43, Newgard shows that the valve opens by insertion of a medical device through the valve, Fig. 2.

Claims 33 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lampropoulos et al. in view of Newgard et al. and further in view of Shoor (US 4,256,116).

Lampropoulos in view of Newgard discloses the invention substantially as claimed. Lampropoulos also discloses the O-ring 34, wherein the engagement feature comprises an O-ring; a syringe adaptor 31. Lampropoulos does not show that the engagement feature 114 comprise an O-ring. Lampropoulos in

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view of Newgard does not show that the syringe adapter 31 including a distal end configured to slide over the tapered proximal end of the connector housing and a proximal opening to receive a male luer.

Shoor discloses a similar catheter system comprising: a catheter 18, a connector, an engagement feature 44 comprises an O-ring 55 in Figs. 1A and 2A. Shoor also discloses that a tapered outer surface of connector at a proximal end, a syringe adapter 48 including a distal end configured to slide over the tapered proximal end 11 of the connector housing and a proximal opening 43 of syringe adaptor 48 to receive a male luer 41. See Figs. 1A-C.

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of Lampropoulos in view of Newgard with an O-ring, as taught by Shoor, in order to prevent leakage of fluid from the interior device.

Claims 42, 46-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lampropoulos et al. in view of Newgard et al. and further in view of Wilson et al. (US 6,921,396).

Lampropoulos in view of Newgard discloses the invention substantially as claimed. Lampropoulos in view of Newgard does not show that a tunneler; wherein the engagement feature 29 engages a tip of the tunneler upon insertion of the tunneler tip into the proximal portion of the passageway; the engagement feature includes a projection into the passageway; wherein the projection has a reduce diameter relative to an inside diameter of the passageway on a proximal side and a distal side of the projection.

Wilson discloses a catheter assembly comprising: a catheter 14; a connector 12 including an engagement feature 12d, 32, 52 engages a tip 42, 49 of the tunneler 40 upon insertion of the tunneler tip into the proximal portion of the passageway. See Figs. 6-7 11, 13. Wilson further discloses that the engagement feature includes a projection 32 into the passageway 22; wherein the projection 32 has a reduce diameter relative to an inside diameter of the passageway on a proximal side and a distal side of the projection.

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of Lampropoulos in view of Newgard with a tunneler, as taught by Wilson,

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in order to improve the engagement between the connector and the tunneler and to perform the subcutaneous tunnel procedure, as for interned use.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 30-33, 40-47 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent Nos. 7,578,803. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are not structurally distinguishable from the claims in the patents.

Response to Arguments

Applicant's arguments with respect to claims 30-33, 40-47 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quynh-Nhu H. Vu whose telephone number is 571-272-3228. The examiner can normally be reached on 6:00 am to 3:00 pm.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763

/Quynh-Nhu H. Vu/
Examiner, Art Unit 3763